DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 17, 2014

OsteoVasive, LLC
% Kevin A. Thomas, Ph.D.
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K133827
Trade/Device Name: A-Link Z
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 20, 2014
Received: October 21, 2014

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133827

Device Name

A-Link Z

Indications for Use *(Describe)*

A-Link Z is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral body space.

A-Link Z is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

A-Link Z may be used as a stand alone device when all four (4) vertebral body bone screws are used. If the physician chooses to use fewer than the four (4) screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

OsteoVasive LLC

A-Link Z

K133827

November 13, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	OsteoVasive LLC 14215 Proton Road Dallas, TX 75244 Telephone: +1 (214) 405-2870 Fax: +1 (214) 960-4313
Official Contact	Bryan Cowan President
Representative/Consultant	Kevin A. Thomas, Ph.D. Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	A-Link Z
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral fusion device with integrated fixation
Classification Regulations	21 CFR 888.3080, Class II
Product Code	OVD
Classification Panel	Orthopedic
Reviewing Branch	Anterior Spine Devices Branch

INTENDED USE

A-Link Z is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral body space.

A-Link Z is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

A-Link Z may be used as a stand alone device when all four (4) vertebral body bone screws are used. If the physician chooses to use fewer than the four (4) screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

DEVICE DESCRIPTION

The A-Link Z is a spinal device that is implanted in the intervertebral body space to improve stability of the spine while supporting fusion. Components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy.

The interbody components are manufactured using medical grade polyetheretherketone (PEEK) conforming to ASTM D2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications* or titanium alloy, Ti-6Al-4V ELI conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The PEEK version of the interbody comes with two tantalum markers conforming to ASTM F560 *Standard Specification for Unalloyed Tantalum for Surgical Implant Applications* to facilitate implant placement. The A-Link Z is available in one footprint (36 mm wide). It has an anatomic shape with serrations on the superior and inferior surfaces. The A-Link Z is available in two lordotic angle options (7° and 12°). The 7° lordotic option has heights ranging from 11 mm to 17 mm in 2 mm increments and the 12° lordotic option has heights ranging from 11 mm to 19 mm in 2 mm increments.

The interbody comes with a press fit plate manufactured from titanium alloy, Ti-6Al-4V ELI conforming to ASTM F136. The plate has four screw holes that allow the passage of bone screws.

The 5.0 mm and 5.5 mm diameter bone screws are available in three lengths (20 mm, 25 mm and 30 mm). The screws are manufactured from titanium alloy, Ti-6Al-4V ELI according to ASTM F136. The A-Link Z is fixed to the adjacent vertebral bodies through the use of four screws inserted through anterior screw holes of the implant.

The screws are prevented from backing out after insertion by the attachment of a cover plate and a cover plate screw to the anterior side of the plate. The cover plate and cover plate screw are manufactured from titanium alloy, Ti-6Al-4V ELI according to ASTM F136.

If the physician chooses to use fewer than the four screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine should be used.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: performance testing, engineering analysis and dimensional analysis. Performance testing to demonstrate substantial equivalence included methods described in the standards ASTM F2077 *Test Methods for Intervertebral Body Fusion Devices* and ASTM F2267 *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression.* The following testing was performed:

- Static & Dynamic Compression testing per ASTM F2077
- Static & Dynamic Torsion testing per ASTM F2077
- Static & Dynamic Compression Shear testing per ASTM F2077
- Expulsion testing
- Subsidence testing per ASTM F2267

Static tensile testing also was performed to measure the force required to separate (pull) the device face plate component from the interbody spacer component.

Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent to the following predicate devices:

- SpineSmith Partners, LP, Cynch Spinal System – Visualif Interbody Fusion Implant System (K102090)
- RSB Spine, LLC, InterPlate® (K071922)
- LDR Spine USA, LDR Spine ROI-A Implant System (K110327)
- Spinal USA, Spinal USA Interbody Fusion Device (K080314)
- Lanx, Inc., Lanx Lateral-SA System (K123767)
- Nexxt Spine, LLC, Honour Spacer System (K120345)
- Surgicraft Ltd., Stalif™ TT Intervertebral Body Fusion System (K073109)
- Life Spine, Inc., Life Spine Stand-Alone Spacer System (K091301)
- Titan Spine, LLC, Endoskeleton® TAS (K111626)

The primary predicate device is K102090.

The implants of the subject device, A-Link Z, have footprint, height, and lordotic angle similar to those of implants cleared in K102090, K110327, K080314, K123767, K073109, K091301, and K111626. The screws of the subject device have dimensions similar to those of screws cleared in

K102090, K123767, and K091301. The screw locking mechanism of the subject device is similar to that of devices cleared in K102090, K071922, K123767, and K091301. The materials of the subject device are identical to those of devices cleared in K080314, K123767, K120345, and K111626. The subject device is gamma sterilized similarly to the device cleared in K110327.

CONCLUSIONS

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including length, width, height, and lordotic angle of the implant and length and diameter of the screws. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, A-Link Z has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.